

EXHIBIT 16

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BODY:

Stepping up government investigations into Eli Lilly's marketing of its best-selling drug Zyprexa, state prosecutors in Illinois and Vermont have demanded that the company turn over information about the way it promoted the medication.

On Thursday, lawyers from the consumer protection division of the Illinois attorney general's office demanded that Lilly hand over marketing materials, e-mail messages, and other documents with information about promotion of Zyprexa. Vermont investigators issued a similar order yesterday morning.

The orders are the civil equivalents of criminal subpoenas, according to Deborah Hagan, the chief of the Illinois consumer protection division.

Illinois and Vermont are now part of a coordinated five-state civil investigation into the way Lilly promoted Zyprexa, a treatment for schizophrenia and bipolar disorder. The states are investigating whether Lilly tried to hide Zyprexa's risk of causing weight gain and other risks associated with diabetes and whether the company promoted Zyprexa for use in patients who do not have schizophrenia or bipolar disorder.

Federal laws prohibit such so-called "off label" marketing, although doctors may prescribe any drug for any disease that they believe the drug will help.

The orders on Thursday and yesterday are the first formal demands for Lilly documents from state attorneys and they indicate an escalation of the investigation, according to Ms. Hagan and Julie Brill, who is an assistant attorney general in Vermont.

"We can ask for documents; we can ask for answers to questions; and we can ask for people to come in and testify under oath," Ms. Hagan said. Federal prosecutors in Philadelphia have also recently accelerated their own investigation into Lilly's marketing of Zyprexa.

In a statement yesterday, Lilly said it would cooperate with the investigations and had done nothing wrong. "We intend to cooperate with the Illinois attorney general's civil investigative demand relating to Zyprexa," the company said. "We cannot comment further about this or other ongoing investigations."

While the investigation being led by Illinois is civil, other investigations into Lilly's conduct are both civil and

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criminal. Attorneys general in California and Florida may seek to recover Medicaid payments that the states made for Zyprexa. Medicaid represents a sizable percentage of the drug's overall sales because many people who take the medicine are disabled and do not work.

Any fine or cost recovery could be sizable, because Zyprexa has been a commercial success. The drug is by far Eli Lilly's largest-selling product, with sales of \$4.2 billion last year and about \$30 billion since its introduction in 1996. More than 20 million people have taken Zyprexa since Lilly began selling the drug.

The investigations could continue for months or possibly years, people involved in the cases say, as investigators sift through tens of thousands of documents from the company and talk to current and former employees.

Zyprexa, whose generic name is olanzapine, is a potent chemical that binds with receptors in the brain to reduce the symptoms of schizophrenia and bipolar disorder. But Zyprexa also causes severe weight gain and changes in blood sugar and cholesterol in many patients who take it.

Internal Lilly documents provided to The New York Times last month by a lawyer in Alaska who represents people with mental illness indicate that Lilly has engaged in a decade-long campaign to play down the seriousness of the side effects of Zyprexa.

Lilly did not disclose to doctors that its own data showed that 16 percent of people taking Zyprexa for a year gained more than 66 pounds, according to the documents.

The documents also indicate that the company told its drug representatives to promote Zyprexa to doctors for the treatment of conditions other than bipolar disorder or schizophrenia.

Lilly has said it did not market Zyprexa off-label and said so again in its statement yesterday.

"Lilly is committed to the highest ethical standards and to promoting our medications only for approved uses," the company said.

But its marketing materials have repeated references to promoting the drug for other uses. And some sales representatives and doctors have also said they believed that the company was marketing off-label.

Still, any criminal prosecution of the company could face a high burden. While settlements of off-label marketing cases have led to large fines, such cases so far have fizzled if they reach juries.

And as long as drug makers comply with federal requirements to provide data about their products to the Food and Drug Administration, companies have a relatively strong defense against criminal prosecution, according to lawyers who are experts in drug marketing.

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